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PATENT & TRADEMARK OFFICE

PATENT APPLICATION

OUR FILE NO. 960565.ORI

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Re App	:	David M. Flynn et al.	: July 28, 2000
S.N.	:	09/139,155	: Art Unit 2833
Filed	:	August 24, 1998	: Examiner Ross Gushi
For	:	ADAPTER INTEGRATED INTO A LEAD BODY	

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Appellants' Brief

REAL PARTY IN INTEREST

The real party in interest in this Appeal is Cardiac Pacemakers, Inc., a Minnesota corporation, having its principal office located at 4100 North Hamline Avenue, Saint Paul, Minnesota 55112, by virtue of an Assignment from the inventors, recorded August 24, 1998, at Reel 9419, Frame 0563.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to the patent owner, the patent owner's legal representative or the inventors which will directly affect or be directly affected by or have a bearing on the Board of Patent Appeals and Interferences in this pending Appeal to the present knowledge of the undersigned.

STATUS OF CLAIMS

The present application was filed on August 24, 1998, including Claims 1-15. A first office action, dated October 1, 1999, rejected all of the claims under 35 U.S.C. § 103. Another copy of the same office action, dated October 15, 1999, was sent to correct a citation to a reference in the earlier office action. Appellants' reply and amendments to the rejection of Claims 1-15 were filed on January 18, 2000. Claims 1-15 were finally rejected in an office action dated February 28, 2000. Appellants traversed the final rejection of the Claims in a response dated April 28, 2000. The office's response, dated May 11, 2000, maintained the prior

rejection. The Notice of Appeal was filed by Appellants on May 30, 2000. No claims have been allowed or cancelled, and thus all of the claims are the subject of this Appeal.

STATUS OF AMENDMENTS

All amendments submitted in this application are believed to have been entered and are presently considered to be of record. The amendments were made in the applicants' reply dated January 18, 2000.

SUMMARY OF THE INVENTION

The invention of the present application relates generally to pacing defibrillation and hybrid lead wires that are connectable to an implantable cardiac rhythm management device, and more particularly relates to a lead design that electrically and mechanically couples two leads to a single port in a header assembly of the implantable device. The lead may be unipolar or multipolar and includes an adapting member formed as part of the lead body, wherein a port is formed in the adapting member suitable for receiving a terminal end of an additional lead. The lead of the present invention is adaptable as a pacing, defibrillation, or hybrid pacing/defibrillation lead.

During the pacing of a patient's heart, it may be desirable to transmit simultaneously from a pulse generator an identical electrical signal through two or more leads electrically coupled to the pulse generator. For example, during congestive heart failure (CHF) therapy it is believed that the left and right ventricles may be effectively paced by transmitting simultaneously the same pacing signal to both the left and right ventricle. The lead of the present invention may be utilized to electrically couple two or more leads to a single port of the pacing device, thereby allowing simultaneous transmission of an identical signal through the leads. Hence, independent pacing signals to the left ventricle and right ventricle leads would not be required to simultaneously pace the left and right ventricles.

Figures 1-3 illustrate generally the lead 10 of the claimed invention. The lead 10 generally includes an adapting member 12, a non-conductive main body 14, at least one lead terminal connector 16, at least one electrode 42 (see Figure 6), at least one conductor 18 and sealing member 20. The housing 22 includes the terminal block 24 and jumper wire 26 embedded therein. The port 28 is formed in the housing 22 and extends from a first end of the housing 22 to an opposite end, intersecting the terminal block 24. The port 28 is adapted for sealably receiving a lead terminal connector of another lead, wherein the terminal pin of its terminal connector engages the terminal block 24. An aperture 34 is formed in the housing 22 extending from an external surface into the housing 22. The aperture 34 is aligned with a set

screw 30 extending into the terminal block 24, wherein the set screw 30 retains the terminal pin of the other lead's terminal connector to the terminal block 24. When the set screw 30 is tightened, the second lead is held in place in contact with the corresponding terminal block 24, thereby insuring mechanical and electrical contact between the lead and terminal block 24. The jumper wire 26 is embedded within the adapting member and interconnects the terminal block 24 to the selected conductor 18. The jumper wire 26 is welded or otherwise attached for electrical conduction between the jumper wire 26 and the terminal block 24.

Figures 4-7 illustrate an alternate embodiment of the invention. The lead 10 in these figures includes an adapting member 12 modified in shape to conform and engage the header 40 of the implantable device. The header 40 is shown having two ports 44 and 46, wherein the port 44 is shown having two terminal blocks 48 and 50 suitable for electrically coupling a bi-polar lead of known suitable construction (see Figure 5). A bore 52 extends through the housing 22 of the adapting member 12 and aligns with port 44 of the header 40. In this manner, a terminal connector of another lead may be coupled to the header. As shown in Figure 7, the adapting member 12 includes the jumper wire 26 embedded within the adapting member 12. A first end of the jumper wire 26 is welded or otherwise attached to the terminal block 24 for electrical conduction between the jumper wire 26 and the terminal block. The other end of the jumper wire 26 is electrically coupled to a junction block 54. The proximal end of the conducting wire 18 is also connected to the junction block 54. Further, a conducting wire 56 electrically couples the terminal pin 32 to the junction block 54. In this manner, both the terminal pin 32 and terminal block 24 are electrically coupled to the conducting wire 18.

Figure 8 illustrates yet another embodiment wherein the lead 10 includes a second electrode 62 coupled to a second conducting wire 58, which in turn is electrically coupled to a second terminal connector 60 in a known suitable manner.

ISSUES ON APPEAL

1. Whether Claims 1-15 are obvious under 35 U.S.C. §103(a) over U.S. Patent 5,413,595 issued to Stutz Jr., in view of U.S. Patent 5,679,026 issued to Fain.

2. Whether Claim 2 is obvious under 35 U.S.C. § 103 over Fain.

3. Whether Claims 4, 5, 11 and 12 are obvious under 35 U.S.C. § 103 over Fain.

GROUPING OF CLAIMS

The rejections based on 35 U.S.C. § 103 have been applied to all of the claims. However, the dependent claims within each group of independent claims incorporate additional features which provide further support for their patentability. Accordingly, it is the belief of the

Appellants that each and every claim should have the ability to stand or fall on its own merits and that the limitations of each should be considered separately.

ARGUMENT

I. OVERVIEW

On appeal is the position taken by the Examiner that Claims 1-15 of the subject patent application are obvious under 35 U.S.C. § 103. The Patent and Trademark Office has the burden under 35 U.S.C. § 103 to establish a prima facie case of obviousness. In re Fine, 5 USPQ.2d 1596 (Fed. Cir. 1988). To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP 2142. See In re Fine, 837 F.2d 1071, 5 USPQ.2d 1596 (Fed. Cir. 1988); Ashland Oil, Inc. v. Delta Resins and Refractories, Inc., 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985); ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 221 USPQ 929 (Fed. Cir. 1984). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based upon the applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991).

Specifically, the Office Action should set forth:

> (A) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate;
>
> (B) the difference or differences in the claim over the applied reference(s);
>
> (C) the proposed modification of the applied references(s) necessary to arrive at the claimed subject matter; and
>
> (D) an explanation why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification.

MPEP 706.02(j). Absent such a showing, the claims cannot properly be rejected under 35 U.S.C.§ 103.

A rejection based on 35 U.S.C. § 103 must rest on a factual basis with the facts being interpreted without hindsight reconstruction of the invention from the prior art. In making this

evaluation, the Examiner has the initial duty of supplying the factual basis for the rejection he or she advances. The Examiner may not, because of doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis. See In re Warner, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967).

II. THE PRIOR ART REFERENCES DO NOT SUGGEST OR TEACH THE CLAIMED INVENTIONS

"To support the conclusion that the claimed combination is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed combination or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." Ex Parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Interfer. 1985). See also, In re Oetiker, 24 USPQ.2d 1443 (Fed. Cir. 1992); Ex Parte Nesbit, 25 USPQ.2d 1817 (Bd. Pat. App. & Interfer. 1992); In re Jones, 21 USPQ.2d 1941 (Fed. Cir. 1992); and In re Rijckaert, 28 USPQ.2d 1955 (Fed. Cir. 1993). Given the fact that: (1) the references alone or in combination do not expressly or impliedly suggest the claimed combination, and (2) the references have been relied upon by the examiner without any line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references, it is submitted that persons of ordinary skill in the art would not find applicant's invention to have been obvious from the prior art.

With respect to the obviousness rejections, the Office Action used two references, the Stutz, Jr. patent and the Fain et al. patent, and reference to "a lead," upon which to base the rejections. These referenced pieces of cited art will be described below.

A. Stutz, Jr. (U.S. Patent 5,413,595)

Stutz, Jr. discloses a device for retaining, sealing and locking a lead into an implantable pulse generator. Stutz does not even include an adapting member, as in the claimed invention. It also does not describe electrically connecting two leads to a single port of a pulse generator, as provided by the claimed invention.

The Stutz reference depicts a pulse generator 20 having a header portion 24 and an enclosed metallic housing or can 22, wherein the header portion 24 includes an orifice 26 for receiving a connector 30 of a lead 32. The lead connector 30 is secured within the orifice 26 by the use of a defeasible active seal and locking mechanism 50, which includes a sphincter seal 52 and a beveled washer 54 which is forced against the sphincter seal 52 upon insertion of a forked clip 56. The forked clip 56 is then inserted into a slot 58 formed within the header 24 in such a

manner that prongs 80 and 82 of the forked clip 56 force the beveled washer 54 to be displaced axially within the orifice 26 of the header portion 24, axially compressing the sphincter seal 52. The axial compression of the sphincter seal 52 causes the sphincter seal 52 to bulge radially, both outward and inward, in a generally symmetrical manner, thereby simultaneously contacting and sealing against the inside wall of the orifice 26 of the header portion 24, and the body of the lead connector 30. The sphincter seal 52 is designed to securely clamp against the smooth cylindrical surface of the lead connector 30. However, upon removal of the forked clip 56, the sphincter seal 52 expands axially and retracts radially, allowing for easy removal of the lead connector 30 from the orifice 26. There is no suggestion or teaching by Stutz to provide a lead with an adapter as part of the lead.

B. Fain et al. (U.S. Patent 5,679,026)

Fain et al. discloses an adapter on the pulse generator of an implantable cardiac stimulation device that is designed to fit different leads. Lead connectors were not standard at the time of the invention, so the adapter allowed different types of leads to be used with a pulse generator. Fain does not, as in the claimed invention, even suggest a lead having an adapting member formed as part of the lead. It also does not describe electrically connecting more than one lead to a single port of the pulse generator, which would allow simultaneous stimulation from more than one lead, or, effectively, different areas of the heart. Fain requires the same number of ports as number of leads used.

The Fain reference depicts a header adapter 40 which is a separately molded part and which is designed to be secured to receiving portions of the header 18 and pulse generator case 12 of an implantable cardiac stimulation device 10 such as a pacemaker or implantable cardioverter-defibrillator, in order to provide a different lead connector port configuration and/or dimensions than that provided by the header 18 of the device. The header adapter 40 has a plurality of adapter lead connector ports 42, 44, 46 and 48 and a plurality of lead connectors 50, 51, 52 and 54 affixed to a rear portion (mounting side) thereof. The lead connectors extend outwardly from the rear portion of the header adapter, and are insertable into corresponding lead connector ports 20, 22, 24 and 26 of the header 18 of the implantable cardiac stimulation device 10 to which the adapter 40 is to be secured. At least one of the plurality of adapter lead connector ports is of a different size than any of the header lead connector ports of the device 10 to which the header adapter 40 is to be secured, and/or the number of adapter lead connector ports is different (greater or less than) the number of header lead connector ports of the device 10 to which the header adapter 40 is to be secured. Two or more leads inserted into the header

adapter lead connector ports can be electrically connected to the same lead connector and/or one or more of the leads inserted into a header adapter lead connector port(s) can each be electrically connected to two or more of the lead connectors.

C. A Lead

As part of one 35 U.S.C. § 103 rejection, the Office Action makes reference to "a lead." The Office Action does not, however, provide any additional information about the type of lead and does not cite a specific reference including describing the "lead" relied on by the examiner. The other two references, Stutz and Fain, refer to leads but neither reference describes or suggests a lead having a lead adapter integrated into the lead body itself.

III. REJECTIONS UNDER 35 U.S.C. § 103

A. The Office Action Improperly Rejects Claims 1-15 as Obvious Over Stutz Jr. in View of Fain

This section addresses the Examiner's first 35 U.S.C. § 103(a) rejection: that Claims 1-15 were unpatentable over Stutz Jr. in view of Fain. The conclusion in the Office Action that it would have been obvious to combine Stutz Jr.'s retention and seal for retaining a lead in an implantable medical device with Fain's header adapter for an implantable medical device is erroneous. There is no suggestion or teaching by Stutz or Fain to combine these devices. Further, the combination of Stutz and Fain does not result in the claimed invention.

There are several other errors in the rejection of Claims 1-15. One such error is that the Examiner based the finding of obviousness on hindsight reasoning, which is impermissible. See In re Warner, 379 F.2d at 1011. A lead adapter integrated into a lead body was neither suggested or taught by Stutz or Fain. A combination of Stutz in view of Fain would result in some variation in the header design, but not in a modified lead. Only hindsight with full knowledge of the present specification and invention results in modifying Stutz and Fain in a manner to make obvious the claimed invention.

The Advisory Office Action provided that "any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning," and that "so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper." (Office Action, dated February 28, 2000, page 6). However, the Office Action failed to provide any evidence to support the assertion of obviousness to one skilled in the art. Since it is impermissible to engage in hindsight

reconstruction of the claimed invention using the applicant's structure as a template and selecting elements from references to fill in the gaps, In re Gorman, 18 U.S.P.Q.2d 1885 (Fed. Cir. 1991), the rejection under 35 U.S.C. § 103 is improper.

Another error with the rejection of Claims 1-15 is that the rejection is based on an unsupportable assumption that it would have been obvious to combine the Fain adapter and the Stutz lead into a unitary lead and adapter. The Examiner relied on the assertion that the use of a one piece construction instead of a two piece lead and adapter construction is an "obvious engineering choice." (Office Action, dated February 28, 2000, page 4). Obviousness, however, cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive to support the combination. In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992); See MPEP 2143.01. Stutz and Fain fail to teach, suggest, or provide incentive for combining the two references in further combination with a lead to make the claimed inventions. In addition, the Office Action does not provide any evidence at all to support the claim of obviousness.

In support of the rejection of Claims 1-15 as an "obvious engineering choice" the Office Action relies on In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965). The rejection in In re Larson, however, was based on a single prior art reference comprising several parts rigidly secured together as a single unit. The court found that it would have been an obvious engineering choice to construct a single part as a single unit. The decision in In re Larson was not based on a combination of references, but rather was based on the teachings of a single reference. Therefore, the In re Larson case should not apply to the subject application in which the Office Action states, without any additional evidence, that the combination of the Stutz and Fain references and a "lead" would have been an "obvious engineering choice[s]."

A third error with regard to this rejection was that there are limitations in Claims 1-15 of the subject application that are not described in Stutz and/or Fain. All limitations of the rejected claims must be found in the prior art. Stutz and Fain do not show or describe all the limitations of the rejected claims. Stutz does not teach an adapting member. It merely teaches a lead retention and seal for an implantable medical device. The Office Action recognizes that Stutz does not teach an adapting member. (Office Action, dated October 1, 1999, page 2). Also, neither Stutz nor Fain teach, suggest or provide motivation for a lead having an adapting member formed as part of the lead. The claimed adapter integrated into a lead body eliminates components. Although the Office Action asserted that a one piece lead and adapter construction

instead of a two piece construction would have been an "obvious engineering design choice," (Office Action, dated February 28, 2000, page 4), the references do not show or make obvious a one piece lead and adapter construction. Further, the claimed jumper wire connecting a terminal block of an adapting member and a conductor of a lead. Stutz does not even include the adapting member, as mentioned above. Fain describes an adapter for a pulse generator header, but there is no jumper wire between the adapter and the conductor of a lead. Thus, neither reference describes electrically connecting two or more leads to a single port of a pulse generator.

Yet another limitation that is missing from the Fain reference that is included in Claims 4, 5, 11 and 12 is an aperture extending through the adapter so that a lead could connect directly to a port on the header through the lead adapter. This missing limitation is also acknowledged by the Office Action. (Office Action, dated October 1, 1999, page 4).

Another error in the rejection of Claims 1-15 is the assertion that although the cited references serve a different purpose and perform a different function than the claimed device, these differences do not bear on the issue of obviousness. The fact that the references serve a different purpose and perform a different function, however, is important to show non-obviousness in this case. See In re Clay, 966 F.2d 656, 659 (Fed. Cir. 1992). Fain's purpose and function is to convert a lead connector port configuration on the header assembly of an implantable cardiac stimulation device to a different port configuration through the use of an adapter. Fain's purpose and function is, therefore, different from the subject application's purpose. One purpose of the subject claimed invention is to provide multiple leads plugged into a single port of an implanted can. The claimed combination of adapter and lead allows a plurality of leads coupled to a single port of the header to simultaneously stimulate independent of the pulse generator hardware.

The purpose and function of Stutz is merely to seal and retain a lead in a header of a pulse generator, which is different from the claimed invention's purpose and function. A function of the claimed invention that is different from both the claimed references is that the claimed configuration also allows the addition of leads without having to remove the pulse generator from the patient.

Another purpose and function of the claimed invention that is different from the cited references is that the subject claimed invention effectively reduces the number of sealing ports in the device, which in turn reduces the chance of corrosion and the need to repair or replace the device. The claimed configuration also reduces the total number of required component parts, thereby reducing the size of the implantable device as a whole.

In sum, the purposes and functions of the claimed invention differ from the cited references and are further evidence of the non-obviousness of the claimed invention. Overall, it would not have been obvious to combine the Fain adapter and the Stutz lead into a unitary lead and adapter, such as is claimed in Claims 1-15. The Office Action has not met the burden of proving a prima facie case of obviousness. Therefore, the 35 U.S.C. § 103 rejection of Claims 1-15 over Stutz in view of Fain should be reversed.

B. The Office Action Improperly Rejects Claim 2 as Obvious Over Fain

This section will address the Examiner's second 35 U.S.C. § 103(a) rejection, which was that Claim 2 was unpatentable with regard to Fain. Actually, the rejection was that Claim 2 was obvious over Fain in combination with "a lead." However, the Office Action does not specify the type of lead, nor does it cite a reference that includes "a lead." Therefore, one important reason that the rejection of Claim 2 is erroneous is the general reference to "a lead" upon which the obviousness rejection was based. "It is important for an examiner to properly communicate the basis for a rejection so that the issues can be identified early and the applicant can be given fair opportunity to reply." MPEP 706.02(j). The Office Action does not provide the type of lead or a specific reference describing such "a lead." Therefore, Appellants were not given a fair opportunity to respond to the rejection.

Claim 2 is not obvious over Fain, nor is it obvious over Fain in combination with "a lead," even though we are not sure what "lead" the Office Action refers to. Claim 2 is not obvious for some of the same reasons as Claims 1-15 are not obvious over Stutz in view of Fain, as described above in Section A. For example, a prima facie case of obviousness has not been established. Obviousness has not been established because, for one, the Office Action relied on hindsight in making the obviousness assertion. Two, obviousness was not established because the reference, Fain, does not teach or suggest the claimed invention. Three, the Office Action does not provide evidence of obviousness. Four, there are limitations in the claimed invention that are not found in the prior art. Fain does not include an adapting member formed as part of a lead. In addition, Fain does not include a jumper wire and does not electrically connect two or more leads to a single port of a pulse generator, as in the claimed invention of the subject application. Five, the purposes and functions of Fain are different than the claimed invention. For example, Fain's purpose and function is to convert a lead connector port configuration on the header assembly of an implantable cardiac stimulation device to a different port configuration through the use of an adapter. The purpose of the subject claimed invention is to provide multiple leads plugged into a single port of an implanted can, which allows a plurality of leads

attached to a single port of the header to be simultaneously stimulated. Additional purposes and functions of the claimed invention that are different from Fain's are discussed above in Section A.

Since Claim 1, as discussed above in Section A, is not obvious, then Claim 2, as a dependent claim that adds additional limitations is also not obvious. However, Claim 2 standing on its own is also not obvious. For example, Claim 2 includes a limitation that the position of the adapter must be on the proximal end of main body of the lead. The lead body in Fain, upon which this rejection is based, does not include an adapter. The adapter in Fain is connected directly to the pulse generator. The terminal pin of the lead connects with the Fain header adapter. Since this limitation is missing from Fain, Claim 2 cannot be found to be obvious in view of Fain, nor in view of Fain in combination with "a lead." Overall, it would not have been obvious to combine the Fain adapter and "a lead" into a unitary lead and adapter. The Office Action did not meet the burden to prove a prima facie case of obviousness. Therefore, the 35 U.S.C. § 103 rejection of Claim 2 as unpatentable over Fain in combination with a lead should be reversed.

C. The Office Action Improperly Rejects Claims 4, 5, 11 and 12 as Obvious Over Fain

This section will address the Examiner's third 35 U.S.C. § 103 rejection. The Office Action rejects Claims 4, 5, 11 and 12 as unpatentable over Fain because, allegedly, the Fain header adapter could be modified in such a way to make the claimed invention obvious. Specifically it was argued that the Fain device could be modified such that the lead connector port and the lead connector could be replaced by an aperture through the adapter so that the adapter would not interfere with another lead connected directly to a port on the header, and that the inclusion of such an aperture would have been a modification of the shape of the adapter which to a person of ordinary skill in the art would have been obvious. Significant is the fact that there is no suggestion or teaching by Fain for such a modification.

There are several errors in the Examiner's rejection of Claims 4, 5, 11 and 12 as being unpatentable because Fain could be modified in such a way to make them obvious. The errors are, again, similar to those discussed in Section A above. Overall, the Claims are not obvious because a prima facie case of obviousness has not been established. The concept of a lead adapter integrated into a lead body cannot be obvious from a reading of Fain, and could only be conceived based upon hindsight with full knowledge of the present specification and invention, which is impermissible. There are also limitations in the claimed invention that are

not found in the prior art. For instance, Fain does not include an adapting member formed as part of a lead. In addition, Fain does not include a jumper wire and does not electrically connect two or more leads to a single port of a pulse generator, as in the claimed invention of the subject application. Also, Fain does not describe an aperture extending through the adapter as claimed in Claims 4, 5, 11 and 12. Further, the purposes and functions of Fain are different from the claimed invention. For example, Fain's purpose and function is to convert a lead connector port configuration on the header assembly of an implantable cardiac stimulation device to a different port configuration through the use of an adapter. The purpose of the subject claimed invention is to provide multiple leads plugged into a single port of an implanted can, which allows a plurality of leads attached to a single port of the header to be simultaneously stimulated. Additional purposes and functions of the claimed invention that are different from Fain's are discussed in Section A.

The Office Action's assertion, that the shape of the Fain adapter could have been modified in any number of obvious ways so that the shape of the adapter would not interfere with other leads being connected directly to the header, is erroneous. The Office Action does not offer any support for this assertion. The desirability of the suggested modification is not believed to be fairly suggested by a reading of Fain itself. Fain describes an adapter having the same number of terminal pins as the number of parts in the header. The mere fact that the prior art may be modified in the manner suggested by the Office Action does not make the modification obvious unless the prior art suggested the desirability of the modification. In re Mills, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990); In re Fritch, 23 USPQ 780 (CAFC 1992). Fain does not teach or suggest the desirability of the aperture or the modification of the shape of the adapter, as provided by the Office Action. Therefore, there is no evidence to support a prima facie case of obviousness with regard to this rejection.

Since independent Claims 1 and 9 are non-obvious, as discussed above in Section A, it necessarily follows that Claims 4, 5, 11 and 12, which are dependent on Claims 1 and 9 and add further limitations, are also non-obvious. Overall, the modification suggested by the Examiner is not suggested or taught in Fain. Fain does not suggest that the adapter could be modified such that one of the lead connector ports and the lead connector could be replaced by an aperture through the adapter so that the adapter would not interfere with another lead connected directly to a port on the header. The inclusion of such an aperture would not have been an obvious modification of the shape of the Fain adapter. In fact, such a modification would render the disclosed device inoperative for its stated purpose. Therefore, the Office Action has not met the

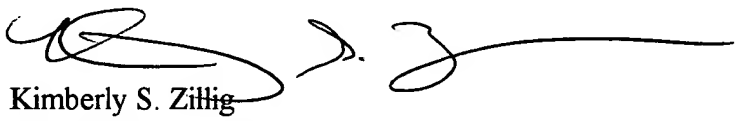
burden to establish a prima facie case of obviousness with respect to Claims 4, 5, 11 and 12 in view of the modification suggested. Furthermore, the 35 U.S.C. § 103 rejection of Claims 4, 5, 11 and 12 should be reversed.

CONCLUSION

The Office Action fails to establish a prima facie case of obviousness. Likewise, none of the proposed combinations, when considered objectively, is suggested by the cited references. Rather, the claimed invention is reached only through a selective reading of the references, inspired by hindsight and contemplating significant modifications neither taught nor suggested by the references. Therefore, a reversal of the rejection of Claims 1-15 is earnestly solicited.

Respectfully submitted,

NIKOLAI, MERSEREAU & DIETZ, P.A.



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APPENDIX A

1. A lead capable of electrical and mechanical coupling to both a port of an implantable medical device's header assembly and to another lead, said lead comprising:

(a) an elongated, main body portion having a proximal and distal end;

(b) at least one terminal connector attached to the proximal end of the main body and adapted for coupling the lead to a header assembly of a medical device;

(c) at least one electrode embodied within the main body portion;

(d) at least one conductor corresponding with each electrode and electrically insulated, wherein a distal end of each conductor is attached to each corresponding electrode and a proximal end of each conductor is attached to at least one corresponding terminal connector;

(e) an adapting member extending from the lead having a port adaptable for sealably receiving a terminal connector of a second lead, said port having an electrically conductive terminal block positioned within said port, wherein a jumper wire is electrically coupled to the terminal block and the conductors of the main body of the lead.

2. The lead as recited in claim 1, wherein said adapting member is positioned on said lead adjacent to the proximal end of the main body.

3. The lead as recited in claim 1, wherein said adapting member engages the header assembly of the implantable medical device.

4. The lead as recited in claim 1, wherein said adapting member has an aperture extending therethrough such that the aperture aligns with a header port when the lead is coupled to the header assembly.

5. The lead as recited in claim 3, wherein said adapting member has an aperture extending therethrough such that the aperture aligns with a header port when the lead is coupled to the header assembly.

6. The lead as recited in claim 3, wherein said adapting member is contoured to conform to a shape of the header assembly.

7. The lead as recited in claim 1, wherein said port of said adapting member is suitable for receiving a terminal end of a uni-polar lead.

8. The lead as recited in claim 1, wherein said jumper wire includes an outer electrically insulating layer and an inner conductive wire.

9. A lead capable of electrical and mechanical coupling to both a port of a header assembly of an implantable medical device and to the terminal end of another lead, said lead comprising:

(a) an elongated, main body portion having a proximal and distal end;

(b) at least one terminal connector attached to the proximal end of the main body and adapted for coupling the lead to a header assembly of a medical device;

(c) at least one electrode embodied within the main body portion;

(d) at least one conductor corresponding with each electrode and electrically insulated, wherein a distal end of each conductor is attached to each corresponding electrode and a proximal end of each conductor is attached to a corresponding terminal connector;

(e) an adapting member extending from said lead adjacent the proximal end of the main body, said adapting member having a port adaptable for sealably receiving a terminal connector of a second lead, said port having an electrically conductive terminal block positioned within said port, wherein a first end of a jumper wire is connected to a terminal block and a second end of said jumper wire is connected to one of the conductors of the main body of the lead.

10. The lead as recited in claim 9, wherein said adapting member engages the header assembly of the implantable medical device.

11. The lead as recited in claim 9, wherein said adapting member has an aperture extending therethrough such that the aperture aligns with a header port when the lead is coupled to the header assembly.

12. The lead as recited in claim 10, wherein said adapting member has an aperture extending therethrough such that the aperture aligns with a header port when the lead is coupled to the header assembly.

13. The lead as recited in claim 10, wherein said adapting member is contoured to conform to a shape of the header assembly.

14. The lead as recited in claim 9, wherein said port of said adapting member is adapted for receiving a uni-polar lead.

15. The lead as recited in claim 9, wherein said jumper wire includes an outer electrically insulating layer and an inner conductive wire.